

Remarks

Claims 1-11 were pending in this application. Claims 9-11 are canceled. Claims 1, 5, and 6 are amended herein. New claims 12-17 have been added.

Support for the amendments of claims 1 and 6 and new claims 12-17 can be found throughout the specification, for example, at page 6, lines 26-32, page 7, lines 1-29 and page 9, lines 18-29. Claim 5 was amended to correct a typographical error.

No new matter is introduced by the foregoing amendments. After entry of this Amendment, **claims 1-8 and 12-17 are pending in this application**. Consideration of the pending claims is requested.

Information Disclosure Statement

Applicants thank Examiner McElwain for considering the references cited on the Information Disclosure Statement submitted to the United States Patent and Trademark Office on April 9, 2007. Applicants note that the Information Disclosure Statement does not indicate that PCT Application No. WO 01/083697 (Exelixis Plant Sciences, Inc.) was considered. Thus, Applicants respectfully request that the Office indicate in a subsequent communication that this reference has been considered.

Elections/Restrictions

Applicants note that the Office has acknowledged the election of Group I, claims 1-8, and that the Office has made the election final. Claims 9-11 are therefore canceled.

Claim Objections

Claim 5 was objected to because the Office action states that there is an absence of a space between “claim” and “1”. Claim 5 has been amended to place a space between “claim” and “1”. In light of this amendment, Applicants respectfully request that this objection be withdrawn.

Rejections under 35 U.S.C. §112, second paragraph:

Claims 1-8 are rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse this rejection.

The Office alleges that claims 1-8 are indefinite in reciting “an ortholog thereof” in relation to SEQ ID NO: 2, because the “use of the term ‘ortholog’ does not set forth the metes and bounds of the claimed invention” (Office action, page 3). Applicants respectfully disagree. However, solely to advance prosecution in this case, Applicants have removed reference to the term “ortholog” from independent claims 1 and 6, thereby making this rejection moot.

The Office also alleges claims 1 and 6, and dependent claims 2-5, 7 and 8, are indefinite because it is “unclear what is encompassed by ‘control plant’” (Office action, page 3). Applicants respectfully disagree, at least because this term would be understood from context by one of skill in the art. However, solely to advance prosecution in this case, claims 1 and 6 have been amended to recite “. . . relative to a plant of the same species that does not comprise the plant transformation vector”. It is clear from Applicants’ disclosure what is encompassed by “a plant that does not comprise a plant transformation vector,” and so the metes and bounds of the claims are clear and definite.

In light of the above arguments and the amendments made herewith, Applicants respectfully request that these indefiniteness rejections of claims 1-8 be withdrawn.

Rejections under 35 U.S.C. §112, first paragraph (written description):

Claims 1-8 are rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse this rejection. In spite of this, and solely to advance prosecution in this case, claims 1 and 6 are amended herewith and it is believed that the amendments clearly overcome the rejection, as discussed below.

The Office alleges that “[t]he specification does not identify any other sequences that produce a high oil phenotype, including any sequences that could be considered orthologs of HIO103.1” (Office action, page 4). Additionally the Office alleges that “the specification does not describe any structural features of the polypeptides that confer any of the recited functional activities or that are required to confer the claimed function of producing a high oil phenotype” (*Id.*). Further, the Office alleges that “Applicants are claiming a genus of sequences. However, only one sequence has been provided” (*Id.*). Based on these statements, the Office concludes that the specification does not provide sufficient written descriptive support for the claims.

Applicants respectfully disagree that more than one sequence is necessary to establish adequate written description for a genus, at least for the following reasons.

As established in *Ex parte Parks*, “adequate description under the first paragraph of 35 U.S.C. 112 does not require literal support for the claimed invention. . . . Rather, it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is claimed” *Ex parte Parks*, 30 USPQ2d 1234, 1236-37 (B.P.A.I. 1993) (emphasis added). Moreover, the MPEP at §2163 states that “[w]hat is conventional or well known to one of skill in the art need not be disclosed in detail. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384; 231 USPQ at 94. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. *See, e.g. Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating “description need not be in *ipsis verbis* [i.e., “in the same words”] to be sufficient”).”

In the current instance, amended claims 1 and 6 recite “a transgenic plant comprising a plant transformation vector comprising a nucleotide sequence that encodes or is complementary to a sequence that encodes a HIO103.1 polypeptide comprising a) the amino acid sequence set forth in SEQ ID NO: 2; or b) an amino acid sequence having at least 95% sequence identity to the amino acid sequence of SEQ ID NO: 2”. This language clearly and structurally describes the molecules that fall within the claimed subject matter. Moreover, the original disclosure clearly

conveys that Applicants had possession of the claimed invention, and certainly of the concept of what is currently claimed. Applicants had possession of the polypeptide sequence in SEQ ID NO: 2; Applicants had also contemplated and provided explicit written description of polypeptides with at least 95% sequence identity to that sequence (for example, at page 9, lines 18-26). Further, the specification describes how to determine which sequences have at least 95% sequence identity to SEQ ID NO: 2 (for example, at page 10, lines 4-27). Methods are also provided for determining which residues are highly conserved (for example, at page 11, line 33 to page 12, line 11); for making polypeptide variants (for example, at page 13, lines 3-8); for the generation of transgenic plants (at page 13, lines 9-11); and for determining if a plant (particularly a transgenic plant) produces a high oil producing phenotype (for example, at page 7, line 1 through 29 and Example 1 on pages 18-19). Therefore, based on the teachings of the specification and the knowledge of one of skill in the art, a person of ordinary skill could envision sequences having at least 95% sequence identity to the sequence set forth in SEQ ID NO: 2. The pending claims are thus sufficiently described by the specification, and Applicants request that the rejection under 35 U.S.C. §112, first paragraph, be withdrawn.

The Office is reminded that the description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. Guidelines for Examination of Patent Applications under the 35 U.S.C. § 112, ¶ 1, “Written Description” Requirement 66 Fed. Reg. 1099, 1106 (2001). Satisfactory disclosure of a “representative number” depends on whether one of skill in the art would recognize that Applicants were in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. *Id.* Applicants respectfully submit that one of skill in the art reading the specification would recognize that Applicants had possession of the claimed invention in its full scope at the time the application was filed. Applicants respectfully request withdrawal of the rejection of claims 1-8, for lack of adequate written description.

Claim Rejections under 35 U.S.C. §112, first paragraph (enablement)

Claims 1-8 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. The claims are rejected because the specification

allegedly “does not reasonably provide enablement for a transgenic plant comprising a plant transformation vector comprising a sequence that encodes the HIO103.1 polypeptide that is an ortholog of the amino acid sequence of SEQ ID NO: 2, and wherein the transgenic plant has a high oil phenotype” (Office action, page 5). Applicants respectfully traverse this rejection. In spite of this, and solely to advance prosecution in this case, claims 1 and 6 are amended, as discussed below. It is believed that the amended claims at least are fully enabled by the specification.

Claim 1 has been amended to be directed to a transgenic plant comprising, in part, “a plant transformation vector comprising . . . an amino acid sequence having at least 95% sequence identity to the amino acid sequence of SEQ ID NO: 2”. Similarly, claim 6 has been amended to be directed to a method of producing a high oil phenotype in a plant, the method comprising in part, “introducing into progenitor cells of the plant a plant transformation vector comprising . . . an amino acid sequence having at least 95% sequence identity to the amino acid sequence of SEQ ID NO: 2”.

The Office asserts that “sequence homology is not enough to predict function of encoded sequences” (Office action, page 6) and further that “identification of related sequences that will encode enzymes having a particular catalytic activity is particularly problematic in the enzymes involved in modifying fatty acids” (*Id.*). Notwithstanding these assertions, Applicants respectfully submit that the claims as amended, in combination with the high degree of skill in the art of molecular biology are fully enabled in light of the teachings of the specification. In particular, the specification (see page 11, line 28 through page 13, line 8) clearly describes methods, which were well known to those of skill in the art at the time the application was filed, for identifying variants, namely:

- (i) Sequence homology analysis, using BLAST and CLUSTAL programs, for example (page 11, line 34 to page 12, line 13);
- (ii) Nucleic acid hybridization (page 12, lines 13-15);
- (iii) Degenerate PCR and screening of a cDNA or genomic library (page 12, lines 15-28); and
- (iv) Antibody binding and expression libraries (page 12, lines 26-31).

The specification also teaches how any identified sequence of interest, such as SEQ ID NO: 2 and sequences having 95% sequence identity to SEQ ID NO: 2 can be used to generate plants with high oil phenotype and how to test for high oil content in transgenic plants transformed with such a sequence. For example, the identified sequence can be cloned into an over-expression vector which in turn can be used to generate transgenic plants that have a high oil phenotype compared to non-transgenic plants (Example 5 at page 28, line 1-17). Taken together, the specification provides enabling support for one of skill in the art to identify a sequence of interest and screen such a sequence for the desired high oil phenotype.

Applicants further submit that mutagenesis and DNA sequencing techniques known in the art at the time the application was filed (see for example, Sacchi *et al.*, *Emerg. Infect. Dis.* 8: 1117-1123, 2002 (Exhibit A); and Wong *et al.*, *Clin. Chem.* 48: 1901-12, 2002 (Exhibit B)), in combination with the large-scale production of transgenic plant lines described in the specification (see for example, page 19, lines 1-7), would allow one of skill in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims.

Thus, Applicants respectfully submit that in view of the teachings of the specification, and the knowledge of one of skill in the art at the time the application was filed, claims 1-8 are fully enabled. In light of the arguments presented above and the amendments of the claims, Applicants request that the rejection of claims 1-8 be withdrawn.

Applicants thank the Examiner for acknowledging that the claims are enabled for transgenic plants comprising a plant transformation vector “comprising the amino acid sequence set forth as SEQ ID NO: 2”. Therefore, claims 13, 14, 16, and 17 are enabled.

Conclusion

Based on the foregoing amendments and arguments, the claims are in condition for allowance and notification to this effect is requested. If for any reason the Examiner believes that a telephone conference would expedite allowance of the claims, please telephone the undersigned at the telephone number listed below.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

One World Trade Center, Suite 1600
121 S.W. Salmon Street
Portland, Oregon 97204
Telephone: (503) 595-5300
Facsimile: (503) 595-5301

By /Tanya M. Harding/
Tanya M. Harding, Ph.D.
Registration No. 42,630